Grant Development Resource
Preparation of a Research Proposal

To help residents and fellows prepare competitive grant applications, the DAGMEC Research Grant Committee recommends applicants use the Research Proposal Outline to complete applications to the DAGMEC Resident and Fellow Research Support Grant. The outline follows a deliberate sequence of reasoning. By carefully responding to each section of the outline, you will be well prepared to complete other research related documents such as protocols to Institutional Review Boards (IRB) or Institutional Animal Care and Use Committees (IACUC).

The research goals and methods of your study will shape the proposal; therefore, emphasize those elements of the outline that apply to your study. The specifics of each section of the outline can be refined as you develop the proposal in consultation with peers, faculty, or co-investigators.

TITLE

- Provide a succinct, but descriptive title.

INVESTIGATORS

- List all investigators, academic degrees, and affiliations including phone number and e-mail addresses.

  The principal investigator is responsible for the overall conduct of the study. While the investigator can delegate activities associated with the study, the responsibility cannot be delegated. The investigators must demonstrate expertise in their field of study, in human subject protection and clinical research, and in the administration of a study.

  A greater degree of documentation and specificity occurs during the research study–including writing the protocol, maintaining study files, and corresponding with funding sources and review bodies, such as the Institutional Review Board (IRB). The IRB will require an updated curriculum vitae from each investigator describing their professional experience.

SUMMARY OR ABSTRACT (complete last)

- State concisely
  - the main purpose of your project
  - your proposed hypothesis or solution
  - the methods for collecting data
  - how you will analyze performance
- Explain the significance of your study
- Describe the setting and the facilities needed

  The abstract is best written after all the other pieces have been completed. It can:

  - provide information for administrative approvals,
  - serve as the written handout to nursing staff or others who need to know about the research,
  - be submitted to meeting or conference planners for presentation.

BACKGROUND AND LITERATURE REVIEW

- Review pertinent literature (a search of MEDLINE must be completed)
- The university and hospital libraries have access to the literature through OHIO Link and the Internet.
- The librarians will help you conduct a search.
- Include references to that literature in your proposal

- Citations from peer-reviewed materials should accompany all significant information discussed in the research proposal. Methods and current practices are especially important to document as well as any novel approaches to the subject matter.
- Reviewers may want to independently confirm the writer's interpretation of a paper, especially when the interpretation is controversial.
- The absence of a complete literature review is the single most common omission in research proposals. Providing documentation of the literature search and a list of references are prerequisites for receiving approval for animal care and use protocols.

SPECIFIC AIMS OR OBJECTIVES

- State the question(s) you want to answer
    - The study question
        - determines the information to be collected during the study
        - influences the methods and the statistics used for analysis. Most statistical tests require that the question be defined before collecting information.
        - prevents bias, especially when studying associations or correlation with an event

SIGNIFICANCE TO PATIENT, INSTITUTION, PROFESSION, OR ALL

- Explain why the research is worthy of time, resources, and funds
    - A study to answer a given question may not be "doable" because even with the answer, no changes to current practices would or could be made or because the research design would be inappropriate.
- Consider the benefits and risks to conducting the study
    - Research that is not be important to an individual, might be important to an institution, a profession, or society.
    - How a particular study fills in knowledge gaps* helps determine the risk/benefit ratio of the research.

*Knowledge gaps are places where information does not exist. For example, we have large knowledge gaps in the use of drugs in children. Much of the dosing is ad hoc, generally based on body weight. Actual information about how children handle specific drugs is missing. Similar knowledge deficiencies exist in other fields, i.e., questions exist for which there currently are no answers.

PRELIMINARY WORK (if available)

- Summarize the result of your preliminary studies
- Use your preliminary data to:
    - show that the research is feasible,
    - strengthen the rationale for the sample size needed to complete the work,
    - sharpen the methodological descriptions,
    - avoid unforeseen pitfalls.
        - For both laboratory and clinical-based research, preliminary results are often important for convincing reviewers to fund the study. Funding sources, such as the DAGMEC Resident & Fellow Research Support Grant, enable investigators to collect preliminary data.

METHODS

- Describe the research design and procedures to be used to accomplish the specific aims of the project,
- Include the means by which the data will be collected, analyzed, and interpreted,
- Describe any new methodology and its advantages over existing methodologies,
- Discuss the potential difficulties and limitations of the proposed procedures,
- Provide a tentative sequence or timetable for the investigation,
- Point out any procedures, situations, or material that may be hazardous to personnel and the precautions to be exercised.

In developing this section of the protocol, it is critical to gain the advice of experienced individuals. Studies that are not properly designed are inappropriate to conduct. The time and effort of the investigator or the reviewers will be wasted if the study cannot answer the question.

Other content areas might include:

- Subjects, sample size needed
- Cost or equipment needs

REFERENCES

- Complete a literature review
- Attach citations for the most pertinent literature

APPENDICES (if needed)

- Include relevant information, such as:
    - data collection forms
    - definitions of data to be abstracted
    - questionnaires
    - informed consent document(s)
    - procedure for obtaining consent*
    - schedule of events
    - cost estimates

*Procedure for obtaining consents: Recognize that informed consent is an entire process; it is not limited to obtaining a signature. When research involves human subjects, the investigator must document (in writing):

- HOW consent will be obtained,
- WHO will ask for consent, and
- HOW the research team will be trained in human subjects concerns.

ADMINISTRATIVE ISSUES

Identify all documents with the date prepared/revised and paginated (e.g., Page 1 of 3). Word processing software offers flexibility with footer or header; macros can be set up to format the first or title page differently.

- Include a line for initials of the research subject on each page of the informed consent documents.
- Highlight and date all changes to the protocol and/or the consent.
- Submit any changes to a protocol to the IRB or IACUC. Their approvals must be obtained before instituting the change.

Last Updated September 10, 2002